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10/629,880	07/29/2003	Harry Leneau	29792-73218	5579

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EXAMINER	
SASAN, ARADHANA	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/629,880
Filing Date: July 29, 2003
Appellant(s): LENEAU, HARRY

Mark C. Reichel
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 05/21/2008 appealing from the Office action mailed 09/24/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The prior art relied on is Pierce (US 6,924,273 B2).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Pierce US 6924273.

Pierce teaches a method of treating or preventing osteoarthritis, joint inflammation and pain by administering to a mammal hyaluronic acid (col. 4, lines 46-55 and col. 5, lines 30-35). The reference teaches using 0.1-0.5 mg of hyaluronic acid per kg of body weight in the composition (col. 9, lines 34-39). The reference teaches the effective amount for canines range from 2-8 mg. The compositions can be in the form of a paste, gel, tablets, and capsules (col. 11, lines 59-60). Example discloses a hyaluronic composition that comprises water as the food acceptable carrier (col. 17, lines 1-15).

(10) Response to Argument

I. Appellant argues that Pierce does not constitute prior art to the present application as the disclosure of the provisional application for which Pierce

claims priority did not sufficiently enable the Pierce non-provisional patent application.

This is not found persuasive because Pierce teaches a method of treating or preventing osteoarthritis, joint inflammation and pain by administering to a mammal hyaluronic acid (Col. 4, lines 46-55 and Col. 5, lines 30-35). This disclosure in the Pierce patent constitutes anticipatory prior art under 35 U.S.C. § 102(e).

A. Appellant presents the procedural history of the Pierce applications including Provisional Application No. 60/237,838 (the '838 Application).

B. Appellant presents the procedural history of the Leneau applications.

C. Appellant argues that the "invention" of the '838 application is clearly a composition containing glucosamine sulfate, chondroitin sulfate, and hyaluronic acid, and not hyaluronic acid alone.

This is not found persuasive because the overall teaching of the Pierce patent (US 6,924,273) is the method of treating or preventing osteoarthritis, joint inflammation and pain by administering to a mammal hyaluronic acid (Col. 4, lines 46-55 and Col. 5, lines 30-35). Moreover, instant claim 1 recites the transitional phrase "consisting essentially of" with respect to "an effective amount of hyaluronic acid". The transitional phrase "consisting essentially of" limits the scope of a claim to the

specified materials or steps "and those that do not materially affect the basic and novel characteristics" of the invention. In re Herz, 537 F.2d 549, 551-52 (CCPA 1976). Absent a clear indication in the specification or claims of what the basic and novel characteristics of the claimed composition actually are, however, the term "consisting essentially of" is construed as being equivalent in meaning to the term "comprising". PPG v. Guardian, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Therefore, the recitation of "consisting essentially of an effective amount of hyaluronic acid" in instant claim 1 is construed as being equivalent to the term "comprising" an effective amount of hyaluronic acid. This interpretation of the claim allows the presence of glucosamine sulfate and chondroitin sulfate in the composition along with hyaluronic acid.

D. Appellant argues that the '838 Application introduced, but did not enable, an orally administrable composition containing an effective amount of hyaluronic acid without also containing glucosamine sulfate and chondroitin sulfate.

The examiner respectfully disagrees with this assertion. The '838 Application discloses the benefit of oral preparation and administration of hyaluronic acid (HA), having a clinical effect by administering the HA orally and eliminating more evasive procedures of administering the HA (such as by injection or IV) (Page 5, lines 5-11). Therefore, the disclosure of the

'838 Application is clearly enabled for a method of relieving joint pain, inflammation and swelling by orally administering a composition of HA.

E. Appellant argues that the only support within the Pierce applications for an orally administrable composition containing an effective amount of hyaluronic acid without glucosamine sulfate and chondroitin sulfate appeared within the '977 Application and not the '838 Application.

The examiner respectfully disagrees with this assertion. Support for an orally administrable composition containing an effective amount of HA without glucosamine sulfate and chondroitin sulfate is found in the '838 Application. The '838 Application discloses the benefit of oral preparation and administration of hyaluronic acid (HA), having a clinical effect by administering the HA orally and eliminating more evasive procedures of administering the HA (such as by injection or IV) (Page 5, lines 5-11). Therefore, the disclosure of the '838 Application clearly has support for a method of relieving joint pain, inflammation and swelling by orally administering a composition of HA.

F. Appellant argues that because the '838 Application did not enable an orally administrable composition containing an effective amount of hyaluronic acid without glucosamine sulfate and chondroitin sulfate, Pierce is not prior art with respect to the present application.

This is not found persuasive because, as stated above in points D & E, the '838 Application is clearly enabled for and has support for a method of relieving joint pain, inflammation and swelling by orally administering a composition of HA. Therefore, Pierce constitutes anticipatory prior art under 35 U.S.C. § 102(e).

II. Appellant argues that the claims of the present application do not claim the same subject matter as Pierce.

Appellant submitted a Declaration of Prior Inventorship in the United States (37 C.F.R. § 1.131) (filed 11/07/2006) to demonstrate that the subject matter of the Application "was conceived and reduced to practice at least by the date November 5, 1999, which is a date earlier than the effective date of U.S. Patent No. 6,924,273, namely October 3, 2000."

This declaration is not sufficient to overcome the 35 U.S.C. § 102(e) rejection since Appellant is claiming the same invention as Pierce (US Patent No. 6,924,273).

A. Appellant argues the method claims.

Appellant lists the elements of method claim 20 and the elements of composition claim 1 of Pierce and submits that claim 20 of Pierce includes composition elements (w) through (z) of claim 1 and that Pierce does not claim the same invention as claimed in Appellant's claim 1. Appellant submits the list of differences between the two claims.

1. Appellant argues that composition element (x) of Pierce requires the composition to be in "gel or paste form" and that this element does not appear in Appellant's claim 1, which does not require the nutritional supplement to be in "gel or paste form."

This is not found persuasive because the broadest, most reasonable interpretation of a "nutritional supplement consisting essentially of an effective amount of hyaluronic acid ... and a food acceptable carrier" (of instant claim 1) includes a nutritional supplement in a gel or paste form.

2. Appellant argues that composition element (z) of Pierce does not appear in Appellant's claim 1, which does not require the nutritional supplement to include any type of "gelling or pasting agent."

This is not found persuasive because the broadest, most reasonable interpretation of a "nutritional supplement consisting essentially of an effective amount of hyaluronic acid ... and a food acceptable carrier" (of instant claim 1) includes a nutritional supplement in a gel or paste form.

3. Appellant argues that claim 20 of Pierce, even when considering the elements of claim 1 of Pierce, does not provide for any specific range of hyaluronic acid or its pharmaceutically acceptable salts.

This is not found persuasive because claim 27 of Pierce provides a therapeutically effective amount of sodium hyaluronate that is in the range

of 10mg to 2000mg. Instant claim 1 recites the limitation of "the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1μg to about 400μg/kg of body weight". If 100kg of body weight is used, the effective amount of hyaluronic acid is 40mg, which is within the range disclosed by Pierce.

B. Appellant argues the composition claims.

Appellant argues that no composition claim of Pierce claims the same invention as claimed in any of Appellant's pending composition claims. Appellant submits that none of the composition claims of Pierce (claims 1-19) need to be considered as relevant to the present inquiry as each claim requires effective amounts of additional ingredients not claimed in Appellant's composition claims.

This is not found persuasive because the instant composition claim 8 contains the transitional phrase "consisting essentially of" with respect to "an effective amount of hyaluronic acid". The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristics" of the invention. In re Herz, 537 F.2d 549, 551-52 (CCPA 1976). Absent a clear indication in the specification or claims of what the basic and novel characteristics of the claimed composition actually are, however, the term "consisting essentially of" is construed as being equivalent in meaning to the term "comprising". PPG v. Guardian,

156 F.3d 1351, 1354 (Fed. Cir. 1998). Therefore, the recitation of "consisting essentially of an effective amount of hyaluronic acid" in instant claim 1 is construed as being equivalent to the term "comprising" an effective amount of hyaluronic acid. This interpretation of the claim allows the presence of glucosamine sulfate and chondroitin sulfate in the composition along with hyaluronic acid.

C. Appellant argues that there is a patentable distinction between the claims of the application and the claims of Pierce.

Appellant argues that because the claims of the Application are patently distinct from the claims of Pierce, the previously submitted Declaration is effective to overcome the rejection under 35 U.S.C. § 102(e).

This declaration is not sufficient to overcome the 35 U.S.C. § 102(e) rejection since Appellant is claiming the same invention as Pierce (US Patent No. 6,924,273).

(1) Appellant argues that Pierce requires the composition to be in "gel or paste form" which is not required by Appellant's claim 1.

(2) Appellant argues that Pierce requires a "pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste" which is not required by Appellant's claim 1.

This is not found persuasive because the broadest, most reasonable interpretation of a "nutritional supplement consisting

essentially of an effective amount of hyaluronic acid ... and a food acceptable carrier" (of instant claim 1) includes a nutritional supplement in a gel or paste form and pharmaceutically acceptable gelling or pasting agents capable of forming a gel or paste.

(3) Appellant argues that "the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1μg to about 400μg/kg of body weight," while Pierce does not provide for any specific range of HA or its pharmaceutically acceptable salts.

This is not found persuasive because if 100kg of body weight is used, the effective amount of hyaluronic acid is 40mg, which is within the range disclosed by Pierce.

Therefore, Appellant's method claims and composition claims are not patentably distinct from the method claims and composition claims of Pierce.

III. Appellant presents the PLUS Search conducted during the prosecution of the Pierce case.

Appellant's argument regarding the claims of Leneau et al. (US 6,607,745 or the '745 Patent) that were not deemed to be material to the prosecution of the Pierce case are not found persuasive because they pertain to a different case and are not relevant to the present case.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Aradhana Sasan/
Examiner, Art Unit 1615

Conferees:

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612